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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,659	06/22/2000	ERNST WAGNER	0652.2050000	1008

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,659

Applicant(s)

WAGNER ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 15-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 7/25/2003 (paper no. 18) is acknowledged and entered into the record.
2. Claims 15-38 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claims 15-38 under 35 USC 112, 1st paragraph as lacking enablement is maintained for the reasons of record. Applicant argues that the instant specification has enabled the use of a tumor vaccine and that the examples drawn to the use of an animal models is sufficient to enable claims to therapeutic compositions and methods of their use. Applicant also argues that the some experimentation is not equivalent to or considered undue and should not preclude the enablement of the instant invention. Further applicant argues that the reference cited to show the unpredictability of the art was taken out of context and that in fact, the reference teaches that tumor vaccines are effective.

Applicant's arguments have been carefully considered but are not found persuasive. The instantly claimed invention is drawn to a tumor vaccine comprising a tumor antigens source and an IFN- γ release system. The specification teaches that the administration of the tumor vaccine to mice inoculated with a tumor cells or pre-immunized with the tumor vaccine prevented the formation of tumors in 37-50% of the mice. However, the population being tested was a pre-determined population with a known tumor type and thus is not indicative of a real world vaccine wherein the

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populations of subjects to receive treatment of the vaccine is not predictable nor readily known in advance of the administration. Reasonable guidance with respect to preventing any cancer relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease. While various antibody-based therapeutics have shown some promising efficacy in the therapy of cancer, (Weiner L.M., Seminars Oncology, Vol. 26, No. 4, Suppl 12, pages 41-50, 1999), a recent review of such therapies did not indicate nor suggest that such therapies would be successful in the prevention of cancer. Thus, although enabling for a composition that is useful as a treatment for cancer, the specification (i.e. working examples) has not provided reasonable guidance so as to teach the skilled artisan how to prevent the formation of cancer with a tumor vaccine. This notion is supported by Evans *et al*.

Applicant argues that the use of Evans *et al* was taken out of context and that in fact, the reference teaches the use of cancer vaccines for the tumor therapy is effective and successful. However, Evans *et al* teaches therapeutic approaches for pre-existing

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tumors and that the use of vaccines to preemptively prevent tumors in a prophylactic manner cannot to date replace standard methods of therapeutic treatment. Further Evans *et al* clearly states that cancer vaccines unlike vaccines for infectious agents are used for therapeutic purposes.

As such, the specification has only enabled a composition for the treatment of tumor comprising a tumor antigen and a IFN- γ releasing system.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 15-17, 22, and 24-30 under 35 USC 102 (b) as being anticipated by Golumbek *et al* is maintained for the reasons of record. Applicant argues that the cited reference does not teach each and every limitation of the claimed invention, namely that the effective dose ranges of IFN- γ included within the claimed tumor vaccine are not taught by Golumbek *et al*. Applicant's arguments have been carefully considered but are not found persuasive because in the absence of evidence to the contrary, the concentrations taught by Golumbek *et al* are within the effective dose ranges that is claimed in the instant invention. As such, the rejection is maintained until the applicant can show otherwise that the concentrations of IFN- γ administered by Golumbek *et al* are not within the effective dose ranges claimed.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 15-20, 22-26, and 28-38 under 35 USC 103(a) as being obvious over Golumbek *et al* in view of Porgador *et al* is maintained for the reasons of

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record. Applicant's arguments are substantial the same as those made for the above 102(b) rejection. Applicant's arguments are not considered persuasive because in the absence of evidence to the contrary, the concentrations taught by Golumbek *et al* are within the effective dose ranges claimed in the instant invention. Porgador *et al* teach combination of tumor associated antigen and cytokine and because Golumbek *et al* state that the use of the tumor antigen source and the cytokine as separate entities are effective, more efficient, and less labor intensive, one of ordinary skill in the art would have found motivation to combine the methods and compositions taught by both Golumbek *et al* and Porgador *et al* to arrive at the instantly claimed invention. Furthermore, reasonable expectation of success was provided because Golumbek *et al* showed that the administration of the IFN- γ and tumor antigen source was already effective in treating tumors.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
October 8, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600